K003599

FEB 1 5 2001

Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 978-749-1000
Telefax: 978-749-1599

Smith+Nephew

**510(k) Summary**

Smith & Nephew Suture Anchor

**Date Prepared:**

November 20, 2000

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

**A. Submitter**

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

**B. Company Contact**

William McCallum
Regulatory Affairs Specialist

**C. Device Name**

| | |
|---|---|
| Trade Name: | Smith & Nephew Suture Anchor |
| Common Name: | Suture Anchor<br>Suture, Nonabsorbable, Polyester |
| Classification Name: | Screw, Fixation, Bone |

**D. Predicate Devices**

Mitek Fastin.

**E. Description of Device**

The Smith & Nephew Suture Anchor is a sterile single use anchor system made from titanium with preattached nonabsorbable braided polyester suture.

## F. Indications For Use

The Smith & Nephew Suture Anchor is indicated for use as a suture anchor to facilitate percutaneous or endoscopic soft tissue procedures. The Smith & Nephew Suture Anchor is indicated for shoulder, foot, ankle, elbow, knee, wrist and hand. Examples of such procedures include:
**Shoulder:** rotator cuff tear repairs, acromioclavicular separation repairs, Bankart lesion repairs, biceps tenodesis, capsular shift or capsulolabral reconstructions, deltoid repairs and SLAP Lesion repairs.
**Knee:** Medial collateral ligament, lateral collateral ligament, posterior oblique ligament or joint capsule to tibia, extra capsular reconstruction, ITB tenodesis, patellar ligament and tendon avulsion repair
**Ankle:** Lateral instability, Medial instability, Midfoot reconstruction, Achilles tendon repair.
**Elbow:** Tennis elbow repair, biceps tendon reattachment
**Wrist:** Scaphonolate ligament reconstruction
**Hand:** Thumb ulnar or radial collateral, TFCC
**Foot:** Hallux valgus reconstruction

## G. Comparison of Technological Characteristics

Both the Mitek Fastin and Smith & Nephew Suture Anchors are intended to be used to fixate soft tissue to bone by the use of titanium anchors and nonabsorbable braided polyester suture. They employ the same technologies, materials, intended uses, and are considered substantially equivalent.

William McCallum

Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2001

Mr. William McCallum
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

Re: K003599
Trade Name: Smith & Nephew Suture Anchor
Regulatory Class: II
Regulation: 888:3040
Product Code: HWC and MBI
Dated: November 20,2000
Received: November 21,2000

Dear Mr. McCallum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003599

510(k) Number :

Device Name: Smith & Nephew Suture Anchor

Indications for Use :

The Smith & Nephew Suture Anchor is indicated for use as a suture anchor to facilitate percutaneous or endoscopic soft tissue procedures. The Smith & Nephew Suture Anchor is indicated for shoulder, foot, ankle, elbow, knee, wrist and hand. Examples of such procedures include:

**Shoulder:** rotator cuff tear repairs, acromioclavicular separation repairs, Bankart lesion repairs, biceps tenodesis, capsular shift or capsulolabral reconstructions, deltoid repairs and SLAP (Superior Labrum Anterior to Posterior) Lesion repairs.

**Knee:** Medial collateral ligament, lateral collateral ligament, posterior oblique ligament or joint capsule to tibia, extra capsular reconstruction, ITB (Iliotibial Band) tenodesis, patellar ligament and tendon avulsion repair

**Ankle:** Lateral instability, Medial instability, Midfoot reconstruction, Achilles tendon repair.

**Elbow:** Tennis elbow repair, biceps tendon reattachment

**Wrist:** Scaphonolate ligament reconstruction

**Hand:** Thumb ulnar or radial collateral, TFCC (Triangular Fibrocartilage Complex)

**Foot:** Hallux valgus reconstruction

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE) Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K003599

Prescription Use X OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)